

§ 73.3128

necessary for the protection of the public health, and therefore, this color additive is exempt from the certification requirements of section 721(c) of the act.

[58 FR 3227, Jan. 8, 1993, as amended at 58 FR 17510, Apr. 5, 1993]

§ 73.3128 Mica-based pearlescent pigments.

(a) *Identity and specifications.* The color additive is formed by depositing titanium or iron salts from a basic solution onto mica, followed by calcination to produce titanium dioxide or iron oxides on mica. Mica used to manufacture the color additive shall conform in identity and specifications to the requirements of § 73.1496(a)(1) and (b).

(b) *Uses and restrictions.* (1) Mica-based pearlescent pigments listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lenses in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements in § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[67 FR 65312, Oct. 24, 2002]

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Subpart A—Foods

Sec.

- 74.101 FD&C Blue No. 1.
- 74.102 FD&C Blue No. 2.
- 74.203 FD&C Green No. 3.
- 74.250 Orange B.
- 74.302 Citrus Red No. 2.
- 74.303 FD&C Red No. 3.
- 74.340 FD&C Red No. 40.

21 CFR Ch. I (4–1–11 Edition)

- 74.705 FD&C Yellow No. 5.
- 74.706 FD&C Yellow No. 6.

Subpart B—Drugs

- 74.1101 FD&C Blue No. 1.
- 74.1102 FD&C Blue No. 2.
- 74.1104 D&C Blue No. 4.
- 74.1109 D&C Blue No. 9.
- 74.1203 FD&C Green No. 3.
- 74.1205 D&C Green No. 5.
- 74.1206 D&C Green No. 6.
- 74.1208 D&C Green No. 8.
- 74.1254 D&C Orange No. 4.
- 74.1255 D&C Orange No. 5.
- 74.1260 D&C Orange No. 10.
- 74.1261 D&C Orange No. 11.
- 74.1303 FD&C Red No. 3.
- 74.1304 FD&C Red No. 4.
- 74.1306 D&C Red No. 6.
- 74.1307 D&C Red No. 7.
- 74.1317 D&C Red No. 17.
- 74.1321 D&C Red No. 21.
- 74.1322 D&C Red No. 22.
- 74.1327 D&C Red No. 27.
- 74.1328 D&C Red No. 28.
- 74.1330 D&C Red No. 30.
- 74.1331 D&C Red No. 31.
- 74.1333 D&C Red No. 33.
- 74.1334 D&C Red No. 34.
- 74.1336 D&C Red No. 36.
- 74.1339 D&C Red No. 39.
- 74.1340 FD&C Red No. 40.
- 74.1602 D&C Violet No. 2.
- 74.1705 FD&C Yellow No. 5.
- 74.1706 FD&C Yellow No. 6.
- 74.1707 D&C Yellow No. 7.
- 74.1707a Ext. D&C Yellow No. 7.
- 74.1708 D&C Yellow No. 8.
- 74.1710 D&C Yellow No. 10.
- 74.1711 D&C Yellow No. 11.

Subpart C—Cosmetics

- 74.2052 D&C Black No. 2.
- 74.2053 D&C Black No. 3.
- 74.2101 FD&C Blue No. 1.
- 74.2104 D&C Blue No. 4.
- 74.2151 D&C Brown No. 1.
- 74.2203 FD&C Green No. 3.
- 74.2205 D&C Green No. 5.
- 74.2206 D&C Green No. 6.
- 74.2208 D&C Green No. 8.
- 74.2254 D&C Orange No. 4.
- 74.2255 D&C Orange No. 5.
- 74.2260 D&C Orange No. 10.
- 74.2261 D&C Orange No. 11.
- 74.2304 FD&C Red No. 4.
- 74.2306 D&C Red No. 6.
- 74.2307 D&C Red No. 7.
- 74.2317 D&C Red No. 17.
- 74.2321 D&C Red No. 21.
- 74.2322 D&C Red No. 22.
- 74.2327 D&C Red No. 27.
- 74.2328 D&C Red No. 28.
- 74.2330 D&C Red No. 30.
- 74.2331 D&C Red No. 31.